DEC STD 203-0 General Requirements for Technical Evaluation Laboratories

DOCUMENT IDENTIFIER: A-DS-EL00203-00-0000 Rev A, 03-Mar-1992

ABSTRACT: This standard describes general requirements for the operation of technical evaluation laboratories within Digital. It contains the minimum requirements for all laboratories to ensure compliance with accepted practices within the industry based on the requirements of ISO/IEC Guide 25 and EN45001 (European norm).

APPLICABILITY: The requirements of this standard are mandatory for all Digital laboratories seeking external agency certification. The external agency may impose requirements in addition to those contained within this standard. This standard is recommended for adoption by all laboratories within Digital as good engineering practice.

STATUS: APPROVED 03-Mar-1992; use VTX SMC for current status.

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REVISION HISTORY:	No previous revision exists.
Document Management Category:	Test Laboratories (HTL)
Responsible Department:	Engineering Operations
Responsible Person:	Eric Williams

APPROVAL: This document has been reviewed and recommended for approval by the General Review group for its category.

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1 INTRODUCTION

Digital's laboratories represent considerable investments in both capital and people. Our laboratories provide a critical resource for the development and manufacture of our products. The quality of these operations must be consistent with the accepted norms and practices within the industry.

This standard provides information on the minimum requirements for the operation of technical evaluation laboratories. *ISO/IEC Guide 25 General requirements for the competence of calibration and testing laboratories* describes these requirements and is included in Appendix A.

External accreditation agencies may require conformance to national or regional standards, for example, in Europe *EN45001 General Criteria for the Operation of Testing Laboratories—1989*. The Digital laboratory seeking external accreditation shall use any additional requirements of the applicable national or regional standards where they differ from ISO/IEC Guide 25.

When conflicts exist between ISO/IEC Guide 25 and the applicable national or regional standards, the laboratory shall contact the owner of DEC STD 203-0 for resolutions. In some cases, the resolutions of these conflicts will be explained under head 3, *DIGITAL SPECIFICS* of this standard.

2 SUMMARY OF BASIC REQUIREMENTS

A list of the subjects covered by the requirements described in ISO/IEC Guide 25 follows.

- Organization of laboratory staff
- Quality system requirements and quality manual
- Laboratory personnel qualifications
- Laboratory environment
- Laboratory equipment
- Measurement traceability and calibration
- Calibration and test methods
- Test samples
- Maintenance of records
- Test certificates and reports
- Subcontracting and outside services

3 DIGITAL SPECIFICS

The following paragraphs provides information that specifically pertains to Digital Equipment Corporation.

3.1 Information Protection

All laboratories must ensure that Digital Proprietary Information is properly protected. Refer to *DEC STD 128-0 Security Classifications for Engineering Intellectual Property—Policy and Regulations*.

Test reports shall be classified and handled at a level of security that is determined by the client. Care is to be taken to ensure proper protection for products that have not been announced.

Test procedures should be written to match procedures accepted within the industry. When procedures are proprietary to Digital, they must be properly protected.

Information pertaining to the qualifications and training of laboratory personnel is to be maintained in accordance with local Digital personnel policies. In general, this information is maintained by the employee's immediate supervisor. Local policies shall apply.

Outside inspection agencies shall have access only to this information with the approval of the local personnel organization, and in accordance with local and corporate personnel policies. Outside inspection agencies shall have access only to this information as necessary for assessing personnel for accreditation purposes and to verify that the qualification and training information is properly maintained by the lab. Under no circumstance shall any employee information such as performance evaluations, salary data, home address, and so forth, be released. For more information, see Personnel Policy 6.18, *Employee Privacy*.

Task descriptions specific to the operation of the laboratory shall be in place. See the examples in *EL-EN103-00 Sample EMC Quality Manual*.

3.2 Domain Responsibilities

Domain responsibilities apply to those disciplines where a technical domain has been established. Refer to *DEC STD 066-1 Technical Domains in the Product Development Process*.

The Technical Domain Manager is responsible for ensuring that the test requirements are defined and documented for the technical discipline. Testing is normally performed in accordance with Digital standards and the adoption of international standards. The Technical Domain Manager shall approve test procedures for all laboratories within the technical domain. The technical domain documentation shall include any requirements that are necessary for laboratory operation and are specific to the domain.

The technical domain documentation shall also include sample test reports for tests conducted within the domain. The sample test reports shall then be modified by the laboratory to meet the specific needs of that laboratory.

Wherever possible, the Technical Domain Manager shall drive the use of common calibration references for use by other laboratories.

The Technical Domain Manager is responsible for the strategy to maintain records of tests performed within the domain.

4 DIFFERENCES—ISO/IEC GUIDE 25 AND EN45001

Additional requirements from EN45001, 1989 are highlighted in the following paragraphs.

4.1 Cooperation with Accreditation Bodies

The testing laboratory shall provide reasonable cooperation to the accreditation body so that the accreditation body may monitor compliance with their requirements.

Representatives of the accreditation body shall have access to relevant areas to witness tests.

Reasonable checks shall be undertaken to enable the accreditation body to verify the capability of the laboratory.

The accreditation body may require the preparation, packaging, and shipment of test samples to verify test results.

The test laboratory may be required to participate in any appropriate program of proficiency testing or comparison testing that the accreditation body deems necessary.

The results of the test laboratory's internal audit and internal proficiency tests shall be made available to the accreditation body.

Particular accreditation bodies may require adherence to their own rules/requirements /interpretations. Such items may include particular requirements relating to the following:

- The uncertainty of measurement
- National standards
- Reporting of results
- Witness testing

4.2 Duties Resulting from Accreditation

EN45001 describes specific responsibilities that the laboratory must accept once it receives accreditation. These responsibilities include the following:

- Comply continually with the requirements of EN45001
- Limit claims of accreditation to those granted by the accreditation body
- Pay application, membership, assessment, surveillance, and other fees as determined by the accreditation body
- Inform the accreditation body of any changes within the laboratory that would affect the testing laboratory's capability or scope of activity
- Restrict use of the accreditation and liability of the accreditation body

APPENDIX A ISO/IEC GUIDE 25: 1990 (E)

General requirements for the competence of calibration and testing laboratories: Third edition 1990

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FOREWORD

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

This third edition of ISO/IEC Guide 25 was drawn up by the ISO Council Committee on conformity assessment (CASCO), in response to a request arising from ILAC '88, the International Laboratory Accreditation Conference held in Auckland (New Zealand) on 17-21 October 1988.

It was approved by the IEC Council in October 1990 and by the ISO Council in December 1990.

The documents produced by CASCO are issued as Guides and follow the general rules for development and promulgation of ISO and IEC standards except that they are the result of a consensus reached within a Council committee, endorsed by the ISO Council and the IEC Council.

The work of ISO/CASCO in preparing Guides uses as a basis the principle that third party certification systems should, to the extent possible, be based on internationally agreed standards and procedures. While recognizing the major role of manufacturers' declaration of conformity through normal manufacturer/customer relationship, Council resolutions have emphasized the preparation of guidance documents on third party conformity assessment procedures in order that national systems may be compatible with one another so as to facilitate bilateral and multilateral agreements.

Whilst these documents are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognizing that some countries may choose to adopt the Guides directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

General requirements for the competence of calibration and testing laboratories

Introduction

Since ISO/IEC Guide 25 was last revised in 1982, the use of quality systemsin laboratories has greatly increased. Many countries have adopted ISO/IEC Guide 25 as the basis both for establishing quality systems in laboratories and for recognizing their competence, for example, by accreditation. In recent years there have been many developments in the field of quality assurance which have led to new and improved guides and standards; it was recognized that there was a need to revise ISO/IEC Guide 25 to reflect these changes.

In this revision of the Guide, attention is paid to the activities of both calibration and testing laboratories and account is taken of other requirements for laboratory competence such as those laid down in the OECD *Code of Good Laboratory Practice* (GLP) and the ISO 9000 series of quality assurance standards.

This Guide should provide a mechanism for promoting confidence in calibration and testing laboratories that can show that they operate in accordance with its requirements.

Acceptance of calibration and test results between countries will facilitate the removal of non-tariff barriers to trade.

The use of this Guide will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, and in the harmonization of standards and procedures.

This Guide is specific to calibration laboratories and testing laboratories.

Laboratories meeting the requirements of this Guide comply, for calibration and testing activities, with the relevant requirements of the ISO 9000 series of standards, including those of the model described in ISO 9002, when they are acting as suppliers producing calibration and test results.

For laboratories engaged in specific fields of testing, such as the chemical field (see, for example, the OECD *Code of Good Laboratory Practice*), or the information technology field, the requirements of this Guide will need amplification and interpretation, as referred to in clause 4.2 of ISO/IEC Guide 55.

1 Scope

1.1 This Guide sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

1.2 Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by the organization or authority granting the recognition (or approval), depending upon the specific character of the task of the laboratory.

1.3 This Guide is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies, and others concerned with the competence of laboratories.

2 References

ISO 8402: 1986, *Quality - Vocabulary*.

ISO 9000: 1987, *Quality management and quality assurance standards—Guidelines for selection and use*

ISO 9001: 1987, *Quality systems—Model for quality assurance in design/development, production, installation and servicing*.

ISO 9002: 1987, *Quality systems—Model for quality assurance in production and installation*.

ISO 9003: 1987, *Quality systems—Model for quality assurance in final inspection and test*.

ISO 9004: 1987, *Quality management and quality system elements—Guidelines*.

ISO/IEC Guide 2: 1986, *General terms and their definitions concerning standardization and related activities*.

International vocabulary of basic and general terms in metrology (vim): 1984, issued by BIPM, IEC, ISO, and OIML.

3 Definitions

The relevant definitions from ISO/IEC Guide 2, ISO 8402, and the *International vocabulary of basic and general terms in metrology* (VIM) are applicable, the most relevant being quoted below together with further definitions applicable for the purposes of this Guide.

3.1 laboratory: Body that calibrates and/or tests.

NOTES

1. In cases where a laboratory forms part of an organization that carries out other activities besides calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process.
2. As used herein, the term "laboratory" refers to a body that carries out calibration or testing
   - — at or from a permanent location,
   - — at or from a temporary facility, or
   - — in or from a mobile facility

3.2 testing laboratory: Laboratory that performs tests.

[ISO/IEC Guide 2—12.4]

3.3 calibration laboratory: Laboratory that performs calibration.

3.4 calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

NOTES

1. The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system or material measure, or the assignment of values to marks on arbitrary scales.
2. A calibration may also determine other metrological properties.
3. The result of a calibration may be recorded in a document, sometimes called a **calibration certificate** or a **calibration report**.
4. The result of a calibration is sometimes expressed as a **calibration factor**, or as a series of calibration factors in the form of a calibration curve.

[VIM - 6.13]

3.5 test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

NOTE - The result of a test is normally recorded in a document sometimes called a **test report** or a **test certificate**.

[ISO/IEC Guide 2 - 12.1, amended]

3.6 calibration method: Defined technical procedure for performing a calibration.

3.7 test method: Defined technical procedure for performing a test.

3.8 verification: Confirmation by examination and provision of evidence that specified requirements have been met.

NOTE - In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore to service, or to perform adjustments, or to repair, or to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed be kept on the measuring instrument's individual record.

3.9 quality system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

[ISO 8402 — 3.8, without the notes]

3.10 quality manual: A document stating the quality policy, quality system and quality practices of an organization.

NOTE - The quality manual may call up other documentation relating to the laboratory's quality arrangements.

3.11 reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

[VIM — 6.08]

3.12 reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

[ISO Guide 30 — 2.1]

3.13 certified reference material (CRM): A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

[ISO Guide 30 — 2.2]

3.14 traceability: The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

[VIM — 6.12]

[A note given in the VIM to this definition applies to the French text only.]

3.15 proficiency testing: Determination of the laboratory calibration or testing performance by means of interlaboratory comparisons.

[ISO/IEC Guide 2 — 12.6, amended]

3.16 requirement: A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

4 Organization and management

4.1 The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Guide.

4.2 The laboratory shall

a. have managerial staff with the authority and resources needed to discharge their duties;

b. have arrangements to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

c. be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

d. specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

e. provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

f. have a technical manager (however named) who has overall responsibility for the technical operations;

g. have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manger or deputy technical manger;

h. nominate deputies in case of absence of the technical or quality manger;

i. where relevant, have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

j. where appropriate, participate in interlaboratory comparisons and proficiency testing programmes.

5 Quality system, audit and review

5.1 The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manger.

5.2 The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Guide. The quality manual and related quality documentation shall also contain

a. a quality policy statement, including objectives and commitments, by top management;

b. the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

c. the relations between management, technical operations, support services and the quality system;

d. procedures for control and maintenance of documentation;

e. job descriptions of key staff and reference to the job descriptions of other staff;

f. identification of the laboratory's approved signatories (where this concept is appropriate);

g. the laboratory's procedures for achieving traceability of measurements;

h. the laboratory's scope of calibrations and/or tests;

i. arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

j. reference to the calibration, verification and/or test procedures used;

k. procedures for handling calibration and test items;

l. reference to the major equipment and reference measurement standards used;

m. reference to procedures for calibration, verification and maintenance of equipment;

n. reference to verification practices including interlaboratory comparisons, proficiency testing programmes, use of reference materials and internal quality control schemes;

o. procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

p. the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;

q. procedures for dealing with complaints;

r. procedures for protecting confidentiality and proprietary rights;

s. procedures for audit and review.

5.3 The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

5.4 The quality system adopted to satisfy the requirements of this Guide shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

5.5 All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

5.6 In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

a. internal quality control schemes using whenever possible statistical techniques;

b. participation in proficiency testing or other interlaboratory comparisons;

c. regular use of certified reference materials and/or inhouse quality control using secondary reference materials;

d. replicate testings using the same or different methods;

e. re-testing of retained items;

f. correlation of results for different characteristics of an item.

6 Personnel

6.1 The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

6.2 The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

6.3 Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

7 Accommodation and environment

7.1 Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

7.2 The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

7.3 The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

7.4 There shall be effective separation between neighbouring areas when the activities therein are incompatible.

7.5 Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

7.6 Adequate measures shall be taken to ensure good housekeeping in the laboratory.

NOTE - It is the laboratory's responsibility to comply with the relevant health and safety requirements. This aspect, however, is outside the scope of this Guide.

8 Equipment and reference materials

8.1 The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Guide are met.

8.2 All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

8.3 Each item of equipment including reference materials shall, when appropriate, be labeled, marked or otherwise identified to indicate its calibration status.

8.4 Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include

a. the name of the item of equipment;

b. the manufacturer's name, type identification, and serial number or other unique identification;

c. date received and date placed in service;

d. current location, where appropriate;

e. condition when received (e.g. new, used, reconditioned);

f. copy of the manufacturer's instructions, where available;

g. dates and results of calibrations and/or verifications and date of next calibration and/or verification;

h. details of maintenance carried out to date and planned for the future;

i. history of any damage, malfunction, modification or repair.

9 Measurement traceability and calibration

9.1 All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established programme for the calibration and verification of its measuring and test equipment.

9.2 The overall programme of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards or measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards or measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

9.3 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable programme of interlaboratory comparisons or proficiency testing.

9.4 Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

9.5 Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a programme of calibration and verification for reference standards.

9.6 Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

9.7 Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

10 Calibration and test methods

10.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

10.2 The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

10.3 Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

10.4 Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

10.5 Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

10.6 Calculations and data transfers shall be subject to appropriate checks.

10.7 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test date, the laboratory shall ensure that:

a. the requirements of this Guide are complied with;

b. computer software is documented and adequate for use;

c. procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

d. computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

e. it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

10.8 Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

11 Handling of calibration and test items

11.1 The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

11.2 Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

11.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

11.4 The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

12 Records

12.1 The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

12.2 All records (including those listed in 8.4 pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

13 Certificates and reports

13.1 The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

13.2 Each certificate or report shall include at least the following information:

a. a title, e.g. "Calibration Certificate", "Test Report" or "Test Certificate";

b. name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

c. unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

d. name and address of client, where appropriate;

e. description and unambiguous identification of the item calibrated or tested;

f. characterization and condition of the calibration or test item;

g. date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

h. identification of the calibration or test method used, or unambiguous description of any non-standard method used;

i. reference to sampling procedure, where relevant;

j. any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to the specific calibration or test, such as environmental conditions;

k. measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

l. a statement of the estimated uncertainty of the calibration or test result (where relevant);

m. a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

n. where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

o. a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.

13.3 Where the certificate or report contains results of calibrations or tests performed by sub-contractors, these results shall be clearly identified.

13.4 Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible.

13.5 Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate [or Test Report or Test Certificate], serial number... [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of clause 12 of this Guide.

13.6 The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

13.7 The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Guide are met and that confidentiality is preserved.

14 Sub-contracting of calibration or testing

14.1 Where a laboratory sub-contracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its sub-contractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being sub-contracted. The laboratory shall advise the client in writing of its intention to sub-contract any portion of the testing to another party.

14.2 The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all sub-contracting.

15 Outside support services and supplies

15.1 Where the laboratory procures outside services and supplies, other than those referred to this guide, in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

15.2 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

15.3 The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

16 Complaints

16.1 The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

16.2 Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Guide or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with 5.3 of this Guide.

APPENDIX B REFERENCED DOCUMENTS

B.1 EL-Class Digital Documents

EL-Class Number	Document Title
EL-00017-01	*DEC STD 017-1 - ISO 9001 - Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing*
EL-00017-02	*DEC STD 017-2 - ISO 9002 - Quality Systems - Model for Quality Assurance in Production and Installation*
EL-00017-03	*DEC STD 017-3 - ISO 9003 - Quality Systems - Model for Quality Assurance in Final Inspection and Test*
EL-00066-01	*DEC STD 066-1 Technical Domains in the Product Development Process*
EL-00128-00	*DEC STD 128-0 Security Classifications for Engineering Intellectual Property — Policy and Regulations*
EL-EN103-00	*Sample EMC Quality Manual*
EL-EX754-00	*ISO 9004 - Quality Management and Quality System Elements - Guidelines*
EL-EX755-00	*ISO 8402 Quality - Vocabulary*
EL-EX756-00	*ISO 9000 - Quality Management and Quality Assurance Standards - Guidelines for Selection and Use*

Use VTX SMC to order copies of EL-class documents from Standards and Methods Control. Send distribution questions to JOKUR::SMC or call DTN: 234-4423.

Use VTX ORANGEBOOK to access Digital *Personnel Policies and Procedures Manual* for Personnel policy 6.18, *Employee Privacy*.

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